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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,030	03/09/2000	James A Thomson	96-0296-96544	4331

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/522,030

Applicant(s)

THOMSON, JAMES A

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12, 14 and 17 is/are rejected.
- 7) ☐ Claim(s) 7 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2004 has been entered.

DETAILED ACTION

This application is an original application filed March 9, 2000.

Applicant's amendment filed February 17, 2004, has been received and entered. Claims 1, 9, 14 and 17 have been amended. Claims 1-14, and 17 are pending and currently under examination.

Response to Amendment

The declaration of Tenneille Ludwig filed February 17, 2004, is found persuasive with respect to the use and ability of other serum supplements to substituted in serum free medium to culture primate embryonic stem cells. In addition, the evidence and remarks presented provide further evidence that other forms of FGF function to maintain primate embryonic stem cells in a undifferentiated and proliferative state.

Specification

As noted in the previous office actions, the use of the trademark KNOCKOUT SR has been noted in this application (page 6; line 22). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-18 of copending Application No. 10/430497 (US Patent application 20030190748). Although the conflicting

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claims are not identical, they are not patentably distinct from each other because each are drawn generally to a method of culturing human embryonic stem cells in serum free conditions wherein the medium is supplemented with FGF.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 recites the limitation "the human basis fibroblast growth factor" in the first line.

There is insufficient antecedent basis for this limitation in the claim or in independent claim 1 from which it depends. Amendment claim 1 to recite a human fibroblast growth factor or reciting a mammalian fibroblast growth factor in claim 8 would obviate the basis of the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-12, 14 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.* ('372), Hogan *et al.* ('926) and Goldsborough *et al.* (FOCUS 20(1):8-12, 1998).

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Initially it is noted that claims 7 and 13 have been removed from the basis of the rejection because they encompass embodiments that were not expected from the combined teachings of Hogan *et al.* ('372), Hogan *et al.* ('926) and Goldsborough *et al.* More specifically, claims 7 and 13 set forth unexpected affects of culturing primate stem cells under the recited conditions.

With respect to the remaining claims, Applicant summarizes the information from the declaration of Ms. Ludwig (page 6) and the basis of rejection set forth by the Examiner (page 7). Applicants argue that in light of the information presented in the declaration of Ms. Ludwig, there is sufficient evidence that the unexpected results now extend to the full breadth of the claims. See Applicant's amendment, pages 6-7. Applicant's arguments have been fully considered, and found persuasive in part.

Initially, as indicated above, Examiner agrees that the information in the declaration of Ms. Teneille Ludwig provides evidence for the ability of other serum supplements to substituted in serum free medium to culture primate embryonic stem cells. Moreover, the evidence and remarks presented provide further evidence that other forms of FGF can be used to culture primate embryonic stem cells. However the claims still broadly encompass culturing the stem cells with any consequence and for any period of time. More specifically, the declaration provides evidence that the conditions maintain primate embryonic stem cells in a undifferentiated and proliferative state, however the claims encompass any consequence of culturing.

As noted in the previous office action, the courts have held that consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed

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invention provides unexpected results. See *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986). Importantly, in this case it is also well established that the evidence presented to rebut a *prima facie* case of obviousness must be commensurate in scope with the claims to which it pertains. See *In re Dill*, 604 F.2d 1356, 1361, 202 USPQ 805, 808 (CCPA 1979). Therefore, the evidence in the instant specification provides support for an unexpected effect of any form of FGF in culturing primate cells with a serum supplement for providing the specific serum free conditions

Therefore, because of the breadth of the instant claims it is maintained that the claimed methods would be obvious over the teachings of Hogan *et al.*, Hogan *et al.* and Goldsborough *et al.* Given the breadth of the instantly claimed methods, there was a reasonable teaching and expectation that the addition of growth factors, in particular the family of FGFs would be necessary in the optimization of growth conditions for embryonic stem cells, and that the addition of these factors would result in better culturing conditions.

Therefore, for the reasons above and of record, the rejection is maintained.

It is noted that if independent claims 1 and 9 were amended in the preamble and final step to reflect the unexpected results of the claimed method it would obviate the basis of the rejection made under 35 USC 103.

Conclusion

No claim is allowed. Claims 7 and 13 are objected to for being dependent on rejected claims.

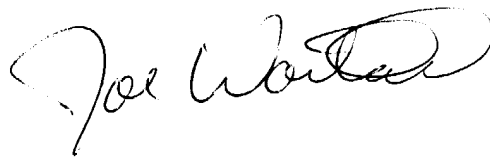
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

A handwritten signature in black ink that reads "Joe Woitach". The signature is written in a cursive, flowing style with a large, stylized initial "J".